

# FOOD AND DRUG ADMINISTRATION

## Center for Drug Evaluation and Research

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety & Risk Management Advisory Committee

### AGENDA

**April 22, 2010**

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Agenda: The committees will discuss new drug application (NDA) 22-451 ACUROX (oxycodone HCl and niacin) Tablets, Acura Pharmaceuticals, Inc., for the proposed indication of relief of moderate to severe pain where the use of an immediate-release, orally administered, opioid analgesic tablet is appropriate, and the results of studies evaluating the addition of niacin, added for the purpose of reducing the misuse of oxycodone.

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8:00 a.m.	Call to Order Introduction of Committee	<b>Jeffery Kirsch, MD</b> Chair, ALSDAC
	Conflict of Interest Statement	<b>Kalyani Bhatt</b> Designated Federal Official, ALSDAC
8:10 a.m.	Opening Remarks	<b>Robert Shibuya, MD</b> Clinical Team Leader, Division of Anesthesia and Analgesia Products CDER/FDA
8:15 a.m.	History of "abuse-deterrent" combination opioids	<b>Frank Pucino, PharmD, MPH</b> Clinical Reviewer Division of Anesthesia and Analgesia Products CDER/FDA
8:30 a.m.	Sponsor Presentations	
	Introduction	<b>Eric G. Carter, PhD, MD</b> Chief Science Officer King Pharmaceuticals, Inc.
	Acurox Tablets Clinical Development Program- Focus on Niacin	<b>Kenneth Sommerville, MD, FAAN</b> Vice President, Clinical Development King Pharmaceuticals, Inc. Adjunct Assistant Professor of Medicine Duke University
	Acurox Tablets Abuse Liability Clinical Studies	<b>Lynn R. Webster, MD, FACPM, FASAM</b> Medical Director Lifetree Clinical Research and Pain Clinic
	Concluding Remarks	<b>Eric G. Carter, PhD, MD</b>
10:00 a.m.	Break	

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10:15 a.m. FDA Presentations

Drug Utilization

**Hina Mehta, PharmD**

Drug Use Analyst  
Office of Surveillance and Epidemiology (OSE)  
CDER/FDA

10:30 a.m. Misuse/Abuse of Opioid Analgesics: Findings from  
The Drug Abuse Warning Network (DAWN)

**Catherine Dormitzer, PhD**

Office of Surveillance and Epidemiology  
CDER/FDA

10:45 a.m. Medication Errors Postmarketing Safety Review  
Of the Manipulation of Oxycodone Immediate-  
Release Products

**L. Shenee' Toombs, PharmD**

Division of Medication Error Prevention  
OSE/CDER/FDA

10:55 a.m. ACUROX Efficacy and Safety

**Igor Cerny, PharmD**

Senior Clinical Analyst  
Division of Anesthesia and Analgesia Products  
CDER/FDA

11:15 a.m. ACUROX Abuse Liability Studies

**Jovita Randall-Thompson, PharmD**

Pharmacologist  
Controlled Substance Staff  
CDER/FDA

**Ling Chen, PhD**

Mathematical Statistician, Special Project Team  
CDER/FDA

12:05 p.m. Lunch

1:00 p.m. Open Public Hearing

2:00 p.m. Questions for the Presenters

2:15 p.m. Break

2:30 p.m. Discussion and Questions to the Committee

4:30 p.m. Adjourn